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UNCLAS BRATISLAVA 000161

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SUBJECT: 2004 SPECIAL 301 REVIEW FOR SLOVAKIA

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¶1. Slovakia has enacted nearly all of the intellectual property legislation required by TRIPS, and the overall IPR situation has improved from a historical perspective. Piracy of optical and other visual medias remains minimal, but home "burning" of CDs has likely increased. The Ministry of Interior and the police have an independent office dedicated to computer-related crime. Although GOS offices and large companies predominantly use licensed software, experts say entrepreneurs and small- and medium-size enterprises continue to use pirated software. The sale of counterfeit trademarked goods is insignificant and we do not believe piracy is a major problem in Slovakia. Authorities have been generally cooperative with aggressive private sector efforts to combat piracy of various products protected by IPR legislation. Only the pharmaceutical sector remains a considerable problem (see paragraphs 3-7).

¶2. Obligations from WIPO's Copyright Treaty (WCT) and WIPO's Performance and Phonograms Treaty (WPPT) were implemented into the Slovak Copyright Act in 2000. Slovakia became party to WCT and WPPT in 2002. In addition, a new Copyright Law (618/2003) came into effect in 2004 and complies with Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society.

¶3. Unfortunately, the pharmaceutical sector continues to be problematic for Slovakia. Of greatest concern is weakness in the field of patent protection. An American company suffered patent infringement by generic drug producers. The American company was granted ten years of patent protection by the GOS at the time it made the decision to enter the product into the Slovak market. (Note: The start date for the ten years began on the date the product was first approved in an EU member country, not in Slovakia. Therefore, approximately six years of patent protection had already expired by the time the product was approved for sale in Slovakia). Subsequently, the GOS changed the period of patent protection to six years, then back to ten (the product qualified as a "high tech" drug), and finally back to six years again. During the first six-year protection period, the patent protection expired and the GOS made sensitive data available to generic competitors. Then, during the time when the patent protection period was returned to ten years, a generic producer was granted approval to enter the Slovak market. Reportedly, the Ministry of Health (MOH) felt this was acceptable because the patent protection period would revert to six years in the near future anyway.

¶4. Numerous other pharmaceutical firms that are innovators of new drugs contend that, according to Slovak law, once a patent right has been given it cannot be changed retroactively. Therefore, the aforementioned American company's patent protection period should be valid for ten years. Because the GOS is solely responsible for approving pharmaceutical products for sale in Slovakia, it must take the lead in patent protection. Unfortunately, it is still unclear which branch of the GOS accepts this responsibility for the pharmaceutical sector.

¶5. As in previous years, data exclusivity protection is a point of contention. The GOS has stored sensitive registration data on the premises of a generic drug producer for years. Reportedly, it managed to move some of the data to a neutral storage facility, but some of it still remains under the care of the generic drug competitor. Although the name on the title of the storage facility was changed, the people involved remain the same.

¶6. American pharmaceutical companies also contend that the GOS violates the EU Transparency Directive by not justifying its decisions regarding the licensing of drugs for sale in Slovakia. Finally, these same companies claim the GOS violates its own laws regarding the maximum allowable time for decision making by various approval committees.

¶7. American pharmaceutical producers report that the situation in Slovakia has improved from previous years. In addition, post is encouraged by new interest on the part of the Slovak Embassy in Washington to make needed changes to be removed from the 301 Watch List. Slovakia's Ambassador has requested, and received, from the Department of Commerce a road map for correcting violations related to the Watch List. However, insufficient progress has been made so far, and post recommends that Slovakia remain on the 301 Watch

List until further improvements are made.
THAYER

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